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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,774	SCHWEIGHOFFER ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the 371 of PCT/FR04/01630 filed December 14, 2005. Claims 1-6 have been cancelled. Amended claims 7-14 are being examined on the merits herein.

Objection

Claim 8 recites, "wherein the compound is a substituted or substituted compound of formula I." The claim should read, "wherein the compound is a substituted or unsubstituted compound of formula I." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cognitive deficits in patients with Alzheimer's disease, does not reasonably provide enablement for the treatment of cognitive deficits in all neurodegenerative diseases. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information that the cognitive deficits of all neurodegenerative diseases are treatable by compounds in the described in the methods claimed.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating the cognitive deficits of patients with any neurodegenerative disease with compounds from the pyrazolopyridine family. The nature of the invention is complex in that it encompasses the treatment of the cognitive deficits of all types of

neurodegenerative diseases.

(2).Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the treatment of the cognitive deficits of all types of neurodegenerative diseases with compounds from the pyrazolopyridine family.

(3).Guidance of the Specification:

All of the guidance provided by the specification is directed toward the treatment of the cognitive deficits of Alzheimer's disease with etazolate.

(4).Working Examples:

Applicant provides examples which indicate that etazolate improves the mnestic and cognitive properties dependent upon the hippocampus, making it possible to reduce the deficits of performance linked to age. As a result, this example provides evidence that etazolate may be employed as a treatment of cognitive problems linked to age such as Alzheimer's disease in particular.

(5).State of the Art.

While the state of the art is relatively high with regard to treating cognitive deficits of Alzheimer's disease, the state of the art with regard to treating the cognitive deficits of

any neurodegenerative disease, generally is underdeveloped. In particular, there is no known treatment agent which is effective against treatment of the cognitive deficits of all neurodegenerative diseases.

There is no such thing as one treatment for all neurodegenerative diseases generally because of their diversity. Thus, it is even beyond the skill of one of extraordinary skill in the art today to obtain an agent to be effective against cognitive deficits in all neurodegenerative diseases generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

(6).Predictability of the Art.

The invention is directed to treatment of the cognitive deficits of any type of neurodegenerative diseases in general. It is well established that "the scope of enablement various inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970).

(7).The Quantity of Experimentation Necessary.

In order to practice the claimed invention, one of skill in the art would have to first envision a combination of an appropriate pharmaceutical carrier, a dosage for each compound, the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would then need to test the combination in the model system to determine whether or

not the combination is effective in treating cognitive deficits in any neurodegenerative disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding treatment of neurodegenerative diseases with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding treatment of neurodegenerative diseases with any compound, the entire, unpredictable process would have to be repeated until successful. In order to practice Applicant's invention, it would be necessary for one to conduct the preceding experimentation for each type of neurodegenerative because there is no known drug effective for inhibiting all types of neurodegenerative diseases. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of treating cognitive deficits in any neurodegenerative disease in a patient by administration of one of the compounds of the "pyrazolopyridine family" within the claims.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, a method for treating cognitive deficits in any neurodegenerative

disease generally by administering the numerous compounds of the "pyrazolopyridine family" of the claims is not considered to be enabled by the instant specification.

Claims 7, 8, and 10-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for some pyrazolopyridine compounds, namely, etazolate and tracazolate, does not reasonably provide enablement for the treatment of any neurodegenerative disease with any pyrazolopyridine compound as set forth in the instant claims. The specification does not provide sufficient information that all pyrazolopyridine compounds are capable of treating cognitive deficits in patients having a neurodegenerative disease. Thus, the term "pyrazolopyridine family" is very broad as cited in claims 7, 8, and 10-12.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of

working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating cognitive deficits in patients having a neurodegenerative disease with the administration of a compound in the pyrazolopyridine family as described in claims 7, 8, and 10-12.

The nature of the invention is complex in that it encompasses the treatment said ailments using a wide array of compounds encompassed by the term "pyrazolopyridine family".

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass methods of treating cognitive deficits in patients having a neurodegenerative disease by administering by a wide array of compounds encompassed the term "pyrazolopyridine family". There are countless possible compounds encompassed by "pyrazolopyridine family" for the treatments claimed. The general definition "pyrazolopyridine family" used in the claims of the present application does not clearly define any chemical compound and is not known in the art to which it pertains. If there is support for a specific compound in the pyrazolopyridine family, the claims must be limited as such. The claims are therefore much broader than the enabling disclosure.

(3). Guidance of the Specification:

The guidance given by the specification as to how effective the disclosed compounds in the pyrazolopyridine family are at treating the desired ailments is limited. Most of the guidance provided by the specification is directed toward *in vitro* studies on etazolate and tracazolate and an *in vivo* on etazolate.

(4). Working Examples:

Applicant provides examples which indicate that etazolate improves the mnestic and cognitive properties dependent upon the hippocampus, making it possible to reduce the deficits of performance linked to age. As a result, this example provides evidence that etazolate may be employed as a treatment of cognitive problems linked to age such as Alzheimer's disease in particular.

(5). State of the Art:

The most pertinent art that the Examiner is aware WO01/78709, WO01/81348, WO01/81345 and WO03/045949 relating to the use of pyrazolopyridines in the treatment of certain events associated with neurological diseases, such as the formation of peptidic aggregates (WO01/78709), phosphorylation of TAU protein (WO01/81348) or blockage of the GSK-3 enzyme (WO01/81345 and WO03/045949).

(6). Nature and predictability of the invention

The nature of the invention is directed towards medicine and is therefore physiological in nature. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a combination of an appropriate pharmaceutical carrier, a dosage for each compound as encompassed by the "pyrazolopyridine family", the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would then need to test the combination in the model system to determine whether or not the combination is effective for treating a patient with a neurodegenerative disease. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding treatment of a neurodegenerative disease with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treat a

neurodegenerative disease by administration of one of the compounds of the "pyrazolopyridine family" as set forth in the instant claims.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, methods of treating a neurodegenerative disease by administering various compounds in the "pyrazolopyridine family" of the claims is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bamdad et al. (WO 01/78709 A2).

Bamdad teaches methods for treating patients susceptible or exhibiting symptoms of a neurodegenerative disease such as Alzheimer's disease (page 5, lines 9-13; page 6, lines 8-12) employing the drug tracazolate (page 26, line 1; Figure 4L), meeting the limitations of claims 7-11.

Bamdad further teaches that oral doses in the range of 50 to 500 milligrams/kg, in one or several administrations per day, will yield the desired results. Dosages may be adjusted appropriately to achieve desired drug levels, local or systemic, depending upon the mode of administration. (page 36, lines 19-27), meeting the limitations of claim 12.

Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikhlef et al. (US Pub. No. 2003/0064374 A1).

Ikhlef teaches treating neurodegenerative diseases, including ALS and Alzheimer's disease with the use of etazolate (page 4, [0056]; claims 9, 12-14, and 17), meeting the limitations of claims 13 and 14.

Conclusion

Claims 7-14 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SJ

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER